

23661. Flour. (F. D. C. No. 39542. S. No. 54-964 M.)

QUANTITY: 140 5-lb. bags and 100 10-lb. bags at Findlay, Ohio.

SHIPPED: Prior to 1953, from Omaha, Nebr.

LIBELED: 8-27-56, N. Dist. Ohio.

CHARGE: 402 (a) (3)—contained insects while held for sale.

DISPOSITION: 10-2-56. Default—destruction.

23662. Flour. (F. D. C. No. 38768. S. No. 11-753 M.)

QUANTITY: 500 140-lb. bags at New Orleans, La.

SHIPPED: 10-25-55, from McPherson, Kans.

LIBELED: 11-17-55, E. Dist. La.

CHARGE: 402 (a) (2)—contained, in interstate commerce, an added poisonous and deleterious substance, benzene hexachloride, which is unsafe within the meaning of the law since it is a substance not required in the production of the article and can be avoided by good manufacturing practice.

DISPOSITION: 7-12-56. Consent—claimed by Biehl & Co., Inc., New Orleans, La. Denatured for use in the manufacture of glue.

23663. Flour. (F. D. C. No. 38767. S. No. 11-752 M.)

QUANTITY: 160 100-lb. bags at New Orleans, La.

SHIPPED: 10-27-55, from Denver, Colo.

LIBELED: 11-17-55, E. Dist. La.

CHARGE: 402 (a) (2)—contained, in interstate commerce, an added poisonous and deleterious substance, benzene hexachloride, which is unsafe within the meaning of the law since it is a substance not required in the production of the article and can be avoided by good manufacturing practice.

DISPOSITION: 7-12-56. Consent—claimed by Biehl & Co., Inc., New Orleans, La. Denatured for use in the manufacture of glue.

23664. Flour. (F. D. C. No. 38766. S. No. 11-751 M.)

QUANTITY: 196 100-lb. bags at New Orleans, La.

SHIPPED: 10-26-55, from Greenville, Tex.

LIBELED: 11-17-55, E. Dist. La.

CHARGE: 402 (a) (2)—contained, in interstate commerce, an added poisonous and deleterious substance, benzene hexachloride, which is unsafe within the meaning of the law since it is a substance not required in the production of the article and can be avoided by good manufacturing practice.

DISPOSITION: 7-12-56. Consent—claimed by Biehl & Co., Inc., New Orleans, La. Denatured for use in the manufacture of glue.

MACARONI AND NOODLE PRODUCTS

23665. Spaghetti. (F. D. C. No. 24883. S. No. 12-958 K.)

QUANTITY: 20 cases, 48 8-oz. pkgs. each, at Wilmington, Del.

SHIPPED: 4-23-48, from New York, N. Y., by Buitoni Products, Inc.

LABEL IN PART: (Pkg.) "Buitoni 20% Protein Spaghetti."

LIBELED: 6-11-48, Dist. Del.

CHARGE: 402 (b) (2)—a product containing added gluten and having a protein content in excess of 13 percent had been substituted for spaghetti; and 403

(g) (1)—the article purported to be and was represented as spaghetti and failed to conform to the definition and standard of identity for spaghetti, as prescribed by regulations.

DISPOSITION: Buitoni Products, Inc., appeared as claimant and filed an answer to the libel, denying that the product was adulterated and misbranded as alleged, on the grounds that the spaghetti manufactured by Buitoni Products, Inc., was not spaghetti within the meaning of the standard for spaghetti, but, instead, a food for which no standard of identity had been established. Motions for summary judgment were filed by the claimant and the Government. The National Macaroni Manufacturers Association entered the case as *amicus curiae*. On September 14, 1954, the motions were heard; and on September 30, 1954, the court entered the following opinion [130 F. Supp. 715]:

LEAHY, Chief Judge: "An article of food labeled 'Buitoni 20% Protein Spaghetti' was seized under 21 U. S. C. § 334 (a). The libel charged the food was misbranded under 21 U. S. C. § 343 (g) (1) as it 'purported to be and was represented as 'a macaroni product, spaghetti, and failed to meet the definition and standard of identity established for that food by the apposite regulations.¹ Libellant charged 'gum gluten' had been added to the spaghetti so that protein content exceeded 13% by weight, when the standard of identity limits maximum protein content to 13% by weight.² Claimant is Buitoni Products, Inc. It admits the seized food was shipped in interstate commerce; 'spaghetti' is a food for which definition and standard of identity has been established under 21 U. S. C. § 341; and the seized food product does not conform to the regulatory requirements as the addition of the 'gum gluten' raises the protein content to 20%. Claimant's defense, which it charges libellant ignores, rests on the fact the seized food is one for which no standard of identity has been established under the Federal Food, Drug, and Cosmetic Act; and that prior to regulatory measures under the Act it had sold and still sells its product, which has 'a distinct and separate identity of its own.' Claimant moved for summary judgment. Libellant filed a cross motion.

"The paper record filed here consists, *inter alia*, of excerpts from the Federal Register which contained administrative findings of fact and regulations relating to macaroni and gluten macaroni hearings; petitions for judicial review filed in 1944-45 by Buitoni Products, Inc., in the Court of Appeals for the Second Circuit in connection with the establishment of standards of identity for alimentary paste; a sample of the seized food; claimant's labeling of the food; and claimant's answers to interrogatories, pre-trial admissions and affidavits.

"The definitions and standards of identity for macaroni products were established at the administrative hearings. In 1941,³ a hearing was held, at which members of the macaroni industry could appear,* to establish definitions and standards of identity for macaroni products, including spaghetti. Claimant appeared as a macaroni manufacturer and showed it was the 'oldest and largest producer of macaroni and similar products in Europe' and that 'the protein content of our spaghetti is 18 to 19 percent.' Claimant's proposals for definitions and standards of identity were rejected.⁴ Claimant filed a petition for judicial review in the Court of Appeals for the Second Circuit. By consent, the petition was dismissed and claimant granted a new hearing by the Federal Security Administrator on the issue of using gum

¹ 21 C. F. R. 16.1.

² 21 C. F. R. 16.1 (a) (5).

³ Administrative Hearing in Washington, November 7, 1941, before the Federal Security Agency—Docket No. F. D. C. 33, pp. 720-23.

*National Macaroni Manufacturers Association, a non-profit trade association which promotes the interest of macaroni products manufacturers, representing 103 companies engaged in the manufacture of macaroni products—approximately 2% of the domestic macaroni products manufacturers and representing by its membership 85% of the national production of macaroni products—was permitted to intervene in these proceedings as *Amicus Curiae*. National Macaroni did not participate at oral argument, but filed its brief supporting the position of the Government for seizure.

⁴ Administrative Findings of Fact Nos. 42, 44, 45 and Conclusion (d).

gluten in order to establish definitions and standards of identity. The second hearing occurred in 1945.⁵ Claimant attempted to have the Administrator recognize gluten as a normal or usual ingredient of macaroni products. On the basis of ample evidence, the Administrator amended the standard of identity and permitted use of gum gluten, but limited its use by specifying total protein content of the finished food product should not exceed 13%. Again, claimant filed a petition for review to the Second Circuit. As the statutory period for review⁶ had lapsed, the case was dismissed.

"The relevant statutory and regulatory provisions are noted in the margin."⁷

"1. Where no genuine issue of fact exists, judgment is authorized by FR 56.⁸ Claimant argues that by utilization of the words '20% Protein' such qualifying label language takes its product from without the administrative standard and permits its sale without regard to such standard; the labeling, in short, yields legal differentiation. Libellant argues claimant's use of an adjectival addition to the usual name of spaghetti, still constitutes legal evasion. Libellant claims the standard and definition, supported by the administrative underlying findings reached in two administrative proceedings, must be accepted as valid. But, libellant argues, even if the administrative standard itself is legally deficient, that issue can not be tested in the proceedings at bar, for the single issue before the Court is whether the form and intent of the standards for spaghetti products precludes the interstate shipment and branding of the product labeled as 'Buitoni 20% Protein Spaghetti.' Precisely, the issue is a narrow one: whether under § 403 (g) claimant's labeled and merchandised product as advertised 'purports to be or is represented as spaghetti.' Based on pleadings, interrogatories, answers, requests for admissions and answers thereto and affidavits, the facts are beyond dispute.

"In addition to the administrative record, it is clear, here, claimant's labels show the name 'spaghetti' in the same size type as '20% protein.' Concededly the product looks like spaghetti in form, length and diameter.⁹ It is similar in color to other brands of spaghetti.¹⁰ Its retail packages are the same general size, shape, and physical appearance as those used by other spaghetti manufacturers.¹¹ It is manufactured from the same raw material as spaghetti.¹²

"While the record shows machinery and equipment used in manufacture are the same as other manufacturers of macaroni products use,¹³ and manner of mixing ingredients of the Buitoni product is the same as used by other manufacturers,¹⁴ the method and process of manufacture utilized are, I think, irrelevant to a determination of the issue to be decided here.

"The product is dried in the same manner as spaghetti made by other manufacturers.¹⁵ Merchandising channels are similar.¹⁶ The product is cooked like

⁵ Administrative Hearing in Washington, October 16, 1945, before the Federal Security Agency, Docket No. F. D. C. 33 (b), pp. 67, 70 and 77.

⁶ 21 U. S. C. § 371 (f).

⁷ 21 U. S. C. § 334 (a): "Any article of food, drug, device or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: * * *"

⁸ 21 U. S. C. § 341: "Whenever in the judgment of the (Federal Security) Administrator such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, * * *"

⁹ 21 U. S. C. § 343 (g): "A food shall be deemed to be misbranded—If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 341, unless (1) it conforms to such definition and standard, * * *"

Code of Federal Regulations, 21 C. F. R. 16.1, pp. 56-62 (1949 ed.), contains the definitions and standards of identity for all alimentary pastes, including spaghetti, duly promulgated pursuant to authority granted in 21 U. S. C. 341, and in accordance with the requirements of 21 U. S. C. 371 (e).

¹⁰ *Sartor v. Arkansas Natural Gas Corp.*, 321 U. S. 620, 627.

¹¹ Request for Admission No. 27.

¹² *Ibid.*, No. 28.

¹³ *Ibid.*, No. 26.

¹⁴ *Ibid.*, Nos. 1, 2 and 3.

¹⁵ *Ibid.*, No. 21.

¹⁶ *Ibid.*, No. 23.

¹⁷ *Ibid.*, No. 25.

¹⁸ *Ibid.*, Nos. 36 and 37.

spaghetti.¹⁷ It is eaten with the same type of cheese and sauce.¹⁸ Customers when ordering spaghetti from claimant's 'Spaghetti Bar' in New York City are served the 'Buitoni 20% Protein Spaghetti.'¹⁹ Claimant also by newspaper and radio advertises its product as spaghetti.²⁰

"2. Congress intended by the enactment of the statutes under consideration promulgation of a standard of identity that even a food product truthfully labeled or including wholesome or beneficial ingredients in a standardized food would be outlawed if forbidden by a valid regulation. The standardization program for classes of foods is the recognition, unless standards of identity are promulgated which limit kinds and ingredients of particular foods, a manufacturer's selection of the various ingredients and combination of ingredients on the basis of varying economic and merchandising considerations—outside the limits of the standard definitions—would result in diversity, both quantitative and qualitative, in the products offered to the public. This does not mean the administrative agency has arbitrary power to ordain the American diet. Substantive limitations and procedural safeguards are available.²¹ The present proceeding is not one to obtain Court review of the reasonableness of the administrative standards.

"Even though labeling may be truthful and informative, this does not in all instances satisfy the requirements of § 343 (g). In *Federal Security Administrator v. Quaker Oats Co.*, 318 U. S. 218, it was decided that even truthful, informative labeling for a product as to which a standard of identity had been promulgated does not justify departure from the standard fixed.²² Here, *Libby, McNeill & Libby v. United States*, 2 Cir., 148 F. 2d 71 (affirming 55 F. Supp. 725), closely governs the present case. In the *Libby* case the standard of identity for tomato catsup made no provision for the use of benzoate of soda as an ingredient. Labeling there specifically declared the food to be 'tomato catsup with preservative.' *Libby* contended the product was not sold as tomato catsup but was sold as tomato catsup with preservative and it was truthfully labeled and named accurately describing its contents; and, therefore, the food product did not purport to be represented as a standard food. The District Court held the product to be misbranded. On affirmance it was held (p. 72) ;

Appellant contends that the label is controlling, that its product does not thereby purport to be catsup, even though it conforms in all respects to the standard, except for the added ingredient. It is a specific article, namely, tomato catsup with preservative, and since its label truthfully so indicates, there is no misbranding. * * * If producers of food products may, by adding to the common name of any such product mere words of qualification or description, escape the regulation of the Administrator,

¹⁷ *Ibid.*, No. 40.

¹⁸ *Ibid.*, Nos. 43 and 47.

¹⁹ *Ibid.*, Nos. 48 and 49.

²⁰ Requests for Admission Appendices A, B, C, D and E; Requests for Admission Nos. 51, 52 and 54.

²¹ The standard of identity must be "reasonable" (21 U. S. C. § 341) and a person adversely affected may have Court review (21 U. S. C. § 371 (f)).

²² At pp. 230-231: "Both the text and legislative history of the present statute plainly show that its purpose was not confined to a requirement of truthful and informative labeling. False and misleading labeling had been prohibited by the Pure Food and Drug Act of 1906. But it was found that such a prohibition was inadequate to protect the consumer from 'economic adulteration,' by which less expensive ingredients were substituted, or the proposition of more expensive ingredients diminished, so as to make the product, although not in itself deleterious, inferior to that which the consumer expected to receive when purchasing a product with the name under which it was sold. * * * The remedy chosen was not a requirement of informative labeling. Rather it was the purpose to authorize the Administrator to promulgate definitions and standards of identity 'under which the integrity of food products can be effectively maintained,' * * * and to require informative labeling only where no such standard had been promulgated, where the food did not purport to comply with a standard, or where the regulations permitted optional ingredients and required their mention on the label * * *."

"The provisions for standards of identity thus reflect a recognition by Congress of the inability of consumers in some cases to determine, solely on the basis of informative labeling, the relative merits of a variety of products superficially resembling each other * * *."

then the fixing of a standard for commonly known foods becomes utterly futile as an instrument for the protection of the consuming public. * * * The present product is intended to satisfy the demand and supply the market for—catsup. Emphasis is laid on its conforming to standard except for the preservative. The argument defeats itself, for if it is an article of food, distinguished from the standard by the qualification, then other ingredients may be added or defined ingredients or processes omitted without conflicting with the regulation, if containers are truthfully labeled. Judge Simons discussed the Quaker Oats case and concluded (p. 73):

Neither the decision nor its rationalization in the Quaker Oats case, can be escaped by a product that looks, tastes, and smells like catsup, which caters to the market for catsup, which dealers bought, sold, ordered, and invoiced as catsup, without reference to the preservative, and which substituted for catsup on the tables of low priced restaurants. The observation in the (Quaker Oats) opinion that it was the purpose of the Congress to require informative labeling, "where the food did not purport to comply with a standard" is not to be lifted out of its context, given a meaning repugnant to the decision, so as to limit "purport" to what is disclosed by the label and to that alone.²³

"3. Claimant in the proceeding at bar relies strongly for absence of misbranding under 21 U. S. C. § 343 (g) on the Supreme Court's most recent decision in 62 Cases of Imitation Jam v. United States, 340 U. S. 593. There it was held the seized jam was an imitation of a standard food and since labeled 'imitation,' as provided by § 403 (c), its action was not prohibitory under § 403 (g). The Imitation case holds, in short, the labeling of a food is controlling if it reveals the food is branded as an imitation in compliance with § 343 (c). The decision is limited to this narrow field. I do not read the opinion as limiting the scope of the Quaker Oats decision—i. e., § 343 (g) is 'not confined to a requirement of truthful and informative labeling.' The crux of the matter is we are not here involved with a labeling of 'imitation spaghetti.' Products may differ in physical characteristics, in composition and labeling so as to be different and to constitute a food product for which no standard of identity has been promulgated by the Administrator. But, again this is not the situation in the case at bar. The seized food is plainly labeled as 'spaghetti.' It looks like spaghetti. It is advertised and merchandised as spaghetti. The present article in the market place contains no distinct subtleties so as to make it an unstandardized product. Clearly, it has no refuge as an imitation product. The conclusion is plain. The seized article of claimant is a spaghetti which does not conform to the standard of identity.

"Claimant's motion for summary judgment is denied. Government's cross motion for summary judgment is granted and the libel sustains forfeiture."

Claimant, Buitoni Foods Corp., subsequently moved for reargument on November 5, 1954. Reargument was heard on February 18, 1955, and the court reaffirmed its previous findings on April 15, 1955, with the following opinion [130 F. Supp. 720]:

ON REARGUMENT

LEAHY, *Chief Judge*: "After the filing of the Court's opinion, D. C. Del., 130 F. Supp. 715, defendant was granted reargument on the question as to whether its basic argument, namely, its product had a separate identity which precluded the application of 21 U. S. C. § 343 (g), should be reconsidered.

"1. It is probable (but true as defendant contends) 'Buitoni 20% spaghetti has a history of separate identity back 100 years prior to the formulation of any regulations or standards.' But I am not convinced the circumstances of production, marketing and consumption of macaroni products in this country

²³ To the same effect, see *United States v. 30 Cases* * * * "Leader Brand Strawberry Fruit Spread," D. C. Iowa, 93 F. Supp. 764; and *United States v. Omar, Inc.*, D. C. Nebr., 91 F. Supp. 121.

dating from the time of the promulgation of the regulations to the present time, permit this separate identity. As shown in the main opinion, the manufacture, appearance and preparation of defendant's product do not yield legal differentiation. Applicability of 21 U. S. C. § 343 (g) is not a historical one, but a practical administrative judgment made from the consumer's standpoint. In short, the standard is not denied application merely because a precise historical tracing will not support it, but because the buying and consuming practices of the public reject its application. Moreover, the administrative record in this case indicates the Federal Security Administrator's ruling limiting gum gluten content to 13% has not been disturbed by any judicial ruling by any court and especially since claimant's petition for review to the Court of Appeals for the Second Circuit was dismissed. Accordingly, I adhere to my original determination defendant's product is controlled by § 343 (g) and may not be brought within the coverage of § 343 (i) as a product for which no standard has been promulgated.

"2. Other points raised by defendant in its reargument are merely variations of its basic contention, i. e., its product has a separate identity. My disposition of the separate identity argument has equal application to the corollaries of defendant's main argument.

"For the reasons stated, the Court reaffirms the conclusions set forth in its opinion of September 30, 1954."

Pursuant to the reargument, the court entered an order on May 13, 1955, for condemnation and destruction. Execution was suspended when the claimant noted an appeal to the United States Court of Appeals for the Third Circuit. The National Macaroni Manufacturers Association again entered the case as amicus curiae. The case was argued on December 8, 1955, and on January 3, 1956, the court of appeals handed down an opinion [228 F. 2d 912] stating that the district court completely and correctly disposed of the case and affirming the opinion of the district court.

The cases of spaghetti were destroyed.

23666. Spaghetti. (F. D. C. No. 39542. S. No. 55-313 M.)

QUANTITY: 7 cases, 12 8-oz. pkgs. each, at Findlay, Ohio.

SHIPPED: On an unknown date, from Bridgeport, Pa.

LIBELED: 8-27-56, N. Dist. Ohio.

CHARGE: 402 (a) (3)—contained insects while held for sale.

DISPOSITION: 11-5-56. Default—destruction.

23667. Macaroni and spaghetti. (F. D. C. No. 39714. S. Nos. 33-661 M; 33-664 M.)

QUANTITY: 5 cases, 24 7-oz. ctns. each, of macaroni, and 4 cases, 24 boxes each, of spaghetti at Parsons, Kans.

SHIPPED: On various dates between 1944 and May 1956, from Kansas City, Mo., and Des Moines, Iowa.

LIBELED: 1-11-57, Dist. Kans.

CHARGE: 402 (a) (3)—contained insects while held for sale.

DISPOSITION: 4-2-57. Default—destruction.

23668. Egg noodles. (F. D. C. No. 39560. S. Nos. 41-032/7 M.)

QUANTITY: 56 cases, 12 1-lb. bags each, and 26 cases, 24 8-oz. bags each, at Mason City, Iowa.

SHIPPED: Between 1-1-55 and 7-5-56, from Milwaukee, Wis.

LIBELED: 9-8-56, N. Dist. Iowa.